Medical Policy
Laser Treatment of Onychomycosis

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Policy Number: 562
BCBSA Reference Number: 2.01.89

Related Policies
- Plastic Surgery, #068

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity
Medicare HMO BlueSM and Medicare PPO BlueSM Members

Laser treatment of onychomycosis is INVESTIGATIONAL.

Prior Authorization Information
Pre-service approval is required for all inpatient services for all products.
See below for situations where prior authorization may be required or may not be required for outpatient services.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

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<tr>
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CPT Codes / HCPCS Codes / ICD-9 Codes
The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.
CPT Codes
There is no specific CPT code for this service.

Description
Onychomycosis is a common fungal infection of the nail. Currently available treatments for onychomycosis, including systemic and topical antifungal medications, have relatively low efficacy and require a long course of treatment. Laser systems are proposed as another treatment option.

Background
Onychomycosis is a common chronic fungal infection of the nail. It is estimated to cause up to 50% of all nail disease and 33% of cutaneous fungal infections. The condition can affect toenails or fingernails but is more frequently found in toenails. Primary infectious agents include dermatophytes (e.g., *Trichophyton* species), yeasts (e.g., *Candida albicans*) and non-dermatophytic molds. In temperate Western countries, infections are generally caused by dermatophytes.

Aging is the most common risk factor for onychomycosis, most likely due to decreased blood circulation, longer exposure to fungi, and slower nail growth. In addition, various medical conditions increase the risk of comorbid onychomycosis. These include diabetes, obesity, peripheral vascular disease, immunosuppression, and HIV infection. In certain populations, onychomycosis may lead to additional health problems. Although there is limited evidence of a causal link between onychomycosis and diabetic foot ulcers, at least one prospective study with diabetic patients found onychomycosis to be an independent predictor of foot ulcer. Moreover, onychomycosis, especially more severe cases, may adversely impact quality of life. Patients with onychomycosis have reported pain, discomfort wearing shoes, nail pressure, and embarrassment.

The diagnosis of onychomycosis can be confirmed by potassium hydroxide preparation, culture or histology. Treatments for onychomycosis include topical antifungals such as nail paints containing ciclopirox (ciclopiroxolamine) or amorolfine, and oral antifungals such as terbinafine and itraconazole. These generally have low to moderate efficacy and a high relapse rate. Topical antifungals and some long-available oral medications such as griseofulvin require a long course of treatment, which presents issues for patient compliance. Moreover, oral antifungal medications have been associated with adverse effects such as a risk of hepatotoxicity.

Several types of device-based therapies are under investigation for treatment of onychomycosis, including ultrasound, iontophoresis, photodynamic therapy and laser systems. A potential advantage of lasers is that they have greater tissue penetration than antifungal medication and thus may be more effective at treating infection embedded within the nail. Another potential advantage is that laser treatments are provided in a clinical setting in only one or several sessions and thus long-term patient compliance is less of an issue than with medications.

Laser treatment of onychomycosis uses the principle of selective photothermolysis. This is defined as the precise targeting of a tissue using a specific wavelength of light. The premise is that light is absorbed into the target area and heat generated by that energy is sufficient to damage the target area while sparing the surrounding area. The aim of laser treatment of onychomycosis is to heat the nail bed to temperatures required to disrupt fungal growth (approximately 40-60°C) and at the same time avoid pain and necrosis to surrounding tissues.

Characteristics of laser systems used to treat onychomycosis are as follows:

**Wavelength:** Lasers are single-wavelength light sources. There needs to be sufficient tissue penetration to adequately treat nail fungus. The near-infrared spectrum tends to be used because this is the part of the spectrum that has maximum tissue penetrance in the dermis and epidermis and the nail plate is similar to the epidermis. To date, most laser systems for treating onychomycosis have been Neodymium
yttrium aluminum garnet (Nd:YAG) lasers that are typically operated at 1064nm; 940-1320nm and 1440nm wavelengths are also options.

**Pulse duration:** Pulses need to be short to avoid damage to the tissue surrounding the target area. For example, short-pulse systems have microsecond pulse durations and Q-switched lasers have nanosecond pulse durations.

**Repetition rate (frequency of laser pulses, Hz):** Selective photothermolysis requires that there be time between pulses to allow for dispersal of heat energy.

**Spot size:** This refers to the diameter of the laser beam. For treating onychomycosis, laser spot sizes range from 1 to 10 nm.

**Fluence:** This refers to the amount of energy delivered into the area and is measured in J/cm²).

A number of laser systems for treating onychomycosis have been cleared for marketing by the U.S. Food and Drug Administration (FDA). The FDA-cleared indications are for the temporary increase of clear nail; they are not cleared as a cure for onychomycosis.

**Summary**
The existing evidence on the efficacy of laser treatment consists of two small RCTs, only one of which included a comparison group that did not receive laser treatment. One of these studies reported improvements in intermediate outcomes such as lineal nail growth, but not in cure of onychomycosis. Moreover, both studies had the methodologic limitation of analyzing the data on a per toe basis, which does not account for correlated measurements. The published evidence to date is insufficient to determine whether laser treatment improves health outcomes in patients with onychomycosis. Additional RCTs are needed that use FDA-cleared devices and compare outcomes to those obtained with a sham control or an alternative treatment for onychomycosis and conduct appropriate statistical analyses. Thus, laser treatment for onychomycosis is considered investigational.

**Policy History**

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**Information Pertaining to All Blue Cross Blue Shield Medical Policies**
Click on any of the following terms to access the relevant information:

- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines

**References**